CASE HP/5-21550/A/CONT

CERTIFICATE OF MAILING

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JAN 24 2005

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF

DIETMAR HÜGLIN ET AL

Alexandria, VA 22313-1450

APPLICATION NO: 10/016,903 FILED: DECEMBER 14, 2001

FOR: USE OF NANODISPERSIONS IN

COSMETIC END FORMULATIONS

Board Of Patent Appeals And Interferences US Patent And Trademark Office P.O. Box 1450 Group Art Unit: 1615

Examiner: G. S. Kishore

2005 JAN 31 MI 10: 30

REQUEST FOR REHEARING UNDER 37 CFR 1.197(b) OF APPEAL NO. 2004-1983

Sir:

In the matter of Appeal No. 2004-1983, the Board of Patent Appeals and Interferences affirmed the rejection of claims 32, 33 and 35-43 under 35 U.S.C. § 103(a) as unpatentable over EP-A 350 150. Appellants respectfully request rehearing of this decision.

The Board's adverse decision is based on an interpretation of page 4 of EP-A 349 150, which teaches mixing of a lipid and a water phase "in an emulsifier, such as a homomixer" (page 4, line 30), and

further teaches an improvement when using a "strong shearing force treatment", which is seen in a device providing "a stronger shearing force than a mixer (e.g. a homomixer...)" (see lines 37 and 38).

From the fact that EP '150 describes the possibility of applying a higher shearing force than a homomixer, and refers to this treatment as "a strong shearing force treatment", the Board concluded that mixing with a homomixer does not involve strong shearing forces and, ergo, is done in the absence of high shear or cavitation forces, thus conforming to the limits of step (ß) of independent claim 32.

This conclusion not unreasonable; however it is **clearly erroneous**. With respect to a homomixer, EP '150 clearly talks about "<u>stronger</u> shearing force than a homomixer" (note the comparative term), which does <u>not</u> imply that a homomixer does not also apply a <u>strong</u> shearing force, or a high shear or cavitation force as excluded by the present claims language. On line 37 of page 4, EP '150 makes an effort to define the term "strong shearing force" in relation to the force applied by a homomixer. This only shows that the inventors of EP '150 have seen the need to define a specific range of shear force as "strong", obviously because this range, as explained in the document, may provide even better results. Naturally, this range, specifically defined for the needs of the subject matter of EP'150, is not necessarily identical with the range of shearing forces usually understood by one skilled in the art as "strong".

The Board members are respectfully directed to paragraph [0046] of U.S. Patent Publication No. US 2004/0266725 A1. Said paragraph reads:

[0046] In the case of using a stirrer having a relatively small shear force, such as the magnetic stirrer or the mechanical stirrer, as the stirring means, a viscosity of the composition to be obtained is reduced with the increase in the shear force (shear speed) as is reported in the aforementioned literature Journal of Biological Macromolecules, 26 (1999), p. 255-261, FIG. 8. In the case of applying a larger shear force by using stress applying means having a large shear force (shear speed) such as the homogenizer (for example, T. K. HOMO MIXER manufactured by Tokushu Kika Kogyo Co., Ltd.), it is preferred to shear the composition with a shear force belonging to a range of shear force which contributes to an increase in viscosity of the product as described in embodiments in detail later in this specification. By employing such method, it is possible to reduce the number or the size of gel particles, thereby enabling to achieve an excellent feel in instillation when the composition is used as an ingredient of eyedrops or, when the composition is used in combination with a function agent, enabling the function agent to exhibit its effect more efficiently.

Note that the T. K. HOMO MIXER is clearly identified as a "stress applying means having a large shear force", as opposed to "a stirrer having a relatively small shear force, such as the magnetic

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stirrer or the mechanical stirrer". A simple magnetic stirrer is used in step (β) of the examples of the present invention.

Four different processes to prepare emulsions are taught in paragraphs [0119] through [1227] of U.S. Patent Publication No. US 2004/0266725 A1. Processes A through C use conventional low shear mixing devices, such as a magnetic stirrer or a mechanical stirrer, while Process D employs the homomixer described above. The subsequent examples demonstrate the superiority of the homomixer versus conventional low shear mixing devices.

As further evidence that a homomixer is not a conventional low shear mixing device, appellants append a copy of a web page describing a commercially available homomixer. It states, "Homomixers are high-speed, high shear batch mixers used for mixing, emulsifying and dispersing".

Appellants also append copies of opinion Declarations by both American and European experts in chemical mixing equipment, who have quite different training and backgrounds. Both declare that a homomixer is a high shear mixing device.

Appellants aver that a homomixer as used in EP-A-349150 is clearly understood by the those skilled in the art as a device to apply a high shear force to a mixture.

For those unfamiliar with chemical processing equipment, the following non-chemical example is offered merely by way of illustration, noting that a Waring Blender, which is commonly used to prepare "frozen" cocktail drinks, is a much less powerful mixing device than a homomixer.

If one mixed all the components of a daiquiri, including the requisite amount of ice cubes, in a Waring Blender, a "frozen daiquiri" would be obtained. But suppose the identical components were simply placed into a glass and stirred with a swizzle stick. Would one expect to obtain a "frozen daiquiri"? Of course not! It would be absolutely amazing to obtain a "frozen daiquiri" without using a high shear mixing device.

Yet what the present inventors have invented is no less than the equivalent of obtaining a "frozen daiquiri" by stirring with a swizzle stick! This must be regarded as surprising and unobvious over EP-A 350 150, which teaches that the final mixing step <u>must</u> be carried out either with a homomixer <u>or</u>

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an even more powerful mixing device, such as a Manton Gaulin homogenizer, which develops substantially higher shear or cavitation forces.

Since mixing with a homomixer is necessarily carried out in the presence of high shear or cavitation forces, and is thus precluded by the limits of process step (ß) in independent claim 32, appellants aver that the rejection of claims 32, 33 and 35-43 under 35 U.S.C. § 103(a) as unpatentable over EP-A 350 150 is based on a fatally flawed interpretation of the sole reference relied upon and should be overturned on rehearing.

Appellants note an additional issue raised by the Board. Remand to the examiner for further action with regard to this issue is deemed appropriate.

Respectfully submitted,

Ciba Specialty Chemicals Corporation Patent Department 540 White Plains Road P.O. Box 2005 Tarrytown, NY 10591-9005 (914) 785-7127 KTM\21550CRehear Kevin T. Mansfield Agent for Appellants Reg. No. 31,635

Enclosures: Form PTO-1449, 1 reference, 2 Declarations

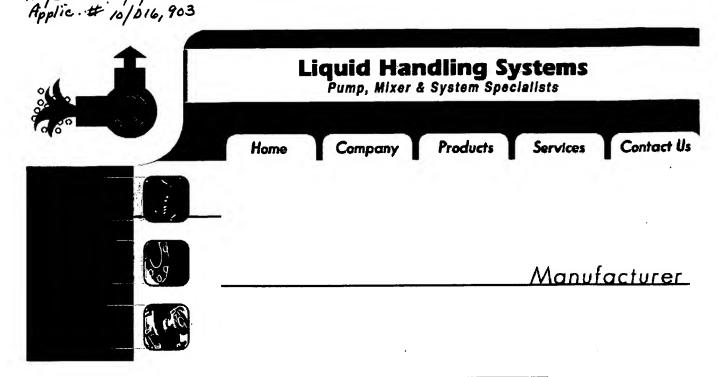
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP §609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

EXAMINER

DATE CONSIDERED





Greerco Homo Mixers

<u>Please Note</u>: Due to contractual obligations, <u>Chemineer</u> products are sold by Liquid Handling Systems <u>only in</u> Southern California and Clark County Nevada.

If you are located outside of the Southern California Area, contact <u>Chemineer, Inc.</u> at Tel: (800) 643-0641 or FAX (508) 687-8500 for an authorized distributor near you. Thank you.

Homomixers are high-speed, high-shear batch mixers used for mixing, emulsifying and dispersing. Characterized by a fixed clearance between the turbine and the stator, the Gifford-Wood homomixer is ideal for fast blending and homogenizing of materials through a wide range of viscosities.

The motor is mounted above the homogenizing head. Blending is accomplished by immersing the homogenizing (turbine-stator) head in a tank or mixing vessel. The speed and patented design of the skewed turbine develop a pressure differential between the bottom of the turbine and the surface of the material



being processed. As a result, unrefined materials are continuously drawn from the bottom of the container and forced to pass through restricted openings in the stator, subjecting the mixture to intense mechanical and hydraulic forces. Mixing time is reduced and a uniform blend assured.

In use, the homomixer is supported on top of the mixing vessel with the mixing head fully immersed below the liquid level. Modifiers such as emulsifiers, wetting agents, etc., may be added, but no other action or attention is required until the processing cycle is completed.

The mixer is also reversible and, in the reverse mode, a strong vortex is formed. The vortex is very useful for entraining and hydrating dry powders, and once the powders are wetted out, the mixer is then operated in the forward mode to homogenize with minimum air entrainment.

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CASE HP/5-21550/A/CONT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF

Group Art Unit: 1615

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Board Of Patent Appeals And Interferences **US Patent And Trademark Office** P.O. Box 1450 Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

Sir:

I, Colleen M. Rocafort, declare as follows:

I hold a Masters in Arts degree in Cosmetic Science from Fairleigh Dickinson University and a Bachelor of Arts degree with certification from the American Chemical Society in Chemistry from Montclair State University.

I am currently the Global Business Head, Polymer Systems for the Home & Personal Care Business Line at Ciba Specialty Chemicals Corporation with overall responsibility to lead the global activities for Polymer and Encapsulation technologies within the Home & Personal Care Business Line. I am also responsible for coordinating the Personal Care global activities of the Regional Technical Service Labs located throughout the world, which involves training the staff on making cosmetic formulations and utilizing various types of mixers to do so.

I have 27 years of varied experience in Cosmetic Science R&D, Product Development, and Analytical Chemistry with specific expertise in Global formulation development and new polymer product development.

I have been active in the cosmetics industry since 1978. I started my career as an Analytical Chemist/Manager for Fluid Packaging Company; spent eleven years of successful and progressive experience as a Group Leader/Scientist in diversified areas of research and development at Playtex Beauty Care, Inc. developing personal care products under the Jhirmack, La Coupe, and Banana Boat brand names; eight years as Director of the Hair Care R&D/Technical Services groups at International Specialty Products developing and introducing new hair fixative and styling polymers and cosmetic formulations for the hair care market; and most recently was Global Head, Personal Care Technical Service and Director of R&D Applications for Polymer Effects & Microencapsulation for Ciba Specialty Chemicals, where I supported the sales, marketing, and R&D groups with new personal care applications and claim support for existing and new products. A large part of my job at Playtex Beauty Care, Inc and International Specialty Chemicals involved the preparation and scale-up of products.

I have been an active member of the Society of Cosmetic Chemists for 24 years. I was elected as the 57th President for the U.S.A. Society of Cosmetic Chemists in 2003; and remain active on several National SCC Committees today.

I am an instructor for five National SCC Continuing Education courses. I instruct students on how to formulate personal care products; two of the courses are Hands-On Lab courses that involve the use of "homomixers".

I am the author/co-author of 22 publications and 12 patents and co-wrote a book chapter on Hair Styling/Fixative Products.

Based on my education and experience, I consider myself to be an expert on making cosmetic formulations, particularly emulsions with "homomixers", and I am familiar with the differences in various types of mixers.

A "homomixer" is a high shear mixer. The advantages of a "homomixer", a high shear rotor/stator batch mixer over simple conventional stirrers or agitators stem from the multi-stage

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mixing/shearing action as materials are drawn through the specially designed workhead - the heart of such machines. The use of such equipment reduces the mixing time to make cosmetic formulations up to 90%. A high shear batch mixer (e.g. a homomixer) doesn't simply mix; it emulsifies, homogenizes, solubilizers, suspends, disperses and disintegrates solids. This type of mixer, with its precision engineered rotor/stator workhead, far outperforms conventional mixers, cutting processing times by up to 90%, improving quality, product consistency and process efficiency.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at High Point, NC on the 20th day of January, 2005 by

Celler m. Rowgart

IN THE UNITED STATES PATENT OFFICE

In re Application of
DIETMAR HÜGLIN ET AL.
Serial No. 10/016,903
Filed December 14, 2001
for: Use of nanodispersions in cosmetic and formulations

DECLARATION UNDER RULE 132

I, Daniel Thibaut, a citizen of France & Switzerland, residing in Blotzheim, France, declare:

that I have studied Chemical Engineering & Chemistry at the "Ecole Supérieure de Chimie Industrielle de Lyon", E.S.C.I.L în France, and that I was awarded the degree of Ingénieur Chimiste ESCIL in 1984;

that I have been employed since 1985 by the company CIBA-GEIGY AG, now Ciba Specialty Chemicals, Basie, Switzerland, as project leader in chemical engineering;

that I presently hold the position of Project Leader for form giving unit operations;

that I have been engaged in the developing of processes for the blending and solidification of light stabilizers and other additives and for aqueous dispersions of them;

that I am an inventor of U.S. Patents assigned to Ciba Specialty Chemicals Inc., in these fields:

5,597,857; 6,225,375; 6,740,694;

and

that the opinion reported below results from my best knowledge.

It was the object of the opinion reported below to describe the operation of a homomixer, as mentioned on page 4 of European Patent Application No. 0349150 and used in examples of European Patent Application No. 0349150, with respect of shearing forces introduced by said device.

Opinion

The term homomixer denotes a high-speed stirrer (rotor-stator principle). It applies high shear forces, whose exact value depends on the type of device employed. Commonly, the highest shear speed of a homomixer is in the range 10'000 to 100'000 s⁻¹.

Final Statement

I, Daniel Thibaut, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Signed, this

1 day of January 2005

Daniel Thibaut